

REMARKS

Claims 21-23 are pending in the application. Claim 21 is amended herein without prejudice and without acquiescence, solely to further the prosecution of this case. Amendments find support in the specification and sequence listing noting that SEQ ID NO:46 is a polypeptide and that prevention of infection is noted at least in the abstract. Applicants reserve the right to pursue amended material in subsequent prosecution.

I. Issues Under 35 U.S.C. §112, second paragraph

Claims 21-23 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter of the invention.

In particular, the Examiner considers the claim vague because the polypeptide is identified by a sequence identification number. Although Applicants consider this language to in fact be very clear, given the nature of a particularly provided sequence, the claim is nevertheless amended herein to further the prosecution of this case.

Furthermore, the Examiner rejects claim 21 as being vague for the recitation of “inhibiting *Ehrlichia canis* infection in a subject prior to exposure or suspected of being exposed to.” The Examiner considers it unclear how to inhibit *E. canis* infection in a subject prior to exposure or suspected of being exposed to an infection because there is no infection to begin with. Applicants assert that the infection can be inhibited by inhibiting it from starting, and therefore the claim is not indefinite. Nevertheless, Applicants amend the claim as suggested by the Examiner solely to further the prosecution of this case.

II. Issues Under 35 U.S.C. §103(a)

Claims 21-23 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ohashi et al. (1998; Infect. Immun., 66:132-139; hereinafter referred to as “Ohashi A”) in view of Ohashi et al. (1998; J. Clin. Microbiol.; hereinafter referred to as “Ohashi B”). Applicants respectfully disagree.

The Examiner fails to make a *prima facie* case of obviousness by failing to note where in Ohashi A there is a teaching or suggestion to employ SEQ ID NO:46 for inhibiting *E. canis* infection, and the Examiner also fails to note where in Ohashi A there is a teaching or suggestion to combine with the subject matter of Ohashi B to achieve Applicants' invention. The Examiner concedes that Ohashi A does not teach a method of inhibiting *E. canis* infection using SEQ ID NO:46 and, in fact, Ohashi A concerns another organism, *Ehrlichia chaffeensis*, and a family of major outer membrane proteins. Although the P28 proteins of *E. chaffeensis* react with the antibody and serum of a 30 kD protein of *E. canis* in the western in FIG. 3 of Ohashi A, there is no indication what the nature of the antigens are in the band therein, and certainly no teaching or suggestion that the *E. chaffeensis* antibody reacts with Applicants' particular SEQ ID NO:46.

The Examiner then characterizes Ohashi B as teaching immunodominant 30-kDa proteins that are immunoreactive with serum from infected animals. The Examiner states that Applicants' SEQ ID NO:46 is nearly identical with the "disclosed prior art protein rP30" and refers Applicants to database Uniprot_05, Accession number Q9ADV2_EHRCA as having one conserved amino acid substitution compared to SEQ ID NO:46. Applicants note there are two sequence differences in the alignment, and not one as indicated by the Examiner.

First, the Q9ADV2_EHRCA database entry was created on June 1, 2001, which is after the priority date of the present application, so this document is not prior art. This document is also contrary to information on the face of Ohashi B that directs one to other sequences. In particular, Applicants refer the Examiner to p. 2673 of Ohashi B under the section, "**GenBank accession number**," wherein Ohashi B states, "The DNA sequences of the *p30*, *p30a*, and *p30-1* genes of *E. canis* have been assigned GenBank accession numbers AF078553, AF078555, and AF078554, respectively."

Applicants provide herewith in a Supplemental Information Disclosure Statement the GenBank entries of AF078553, AF078555, and AF078554. The Examiner will note that AF078555 and AF078554 have been replaced by AF078553. However, none of these GenBank entries discloses SEQ ID NO:46. Curiously, the p30-20 referred to in AF078553 is not the same protein referred to in Q9ADV2_EHRCA, although the Q9ADV2_EHRCA sequence is given this name. More importantly, there is no indication in Ohashi B that rp30

is the sequence p30-20 nor is there any indication that rp30 is Q9ADV2_EHRCA, and there is no rp30 sequence referred to in AF078553, AF078555, or AF078554.

Thus, even if the Q9ADV2_EHRCA database entry had an earlier date, SEQ ID NO:46 or even any sequence having one or two amino acid differences was not disclosed in Ohashi B. Although the alignment provided by the Examiner with sequence Q9ADV2_EHRCA to SEQ ID NO:46 provides a sequence similar but not identical to SEQ ID NO:46, the Q9ADV2_EHRCA sequence is not provided nor is it referred to in Ohashi B.

Moreover, even if the sequence of rP30 were disclosed in Ohashi B, there is no teaching or suggestion for use of Applicants' SEQ ID NO:46 to inhibit *E. canis* infection. The Examiner may be considering that it is obvious from Ohashi A to try some *E. canis* protein for inhibiting infection, but it is not obvious to utilize Applicants' particular SEQ ID NO:46. Applicants thus contend that the Examiner has engaged in an improper hindsight reconstruction, picking and choosing from multiple references that differ in their teachings. "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention." *In re Fina*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

Applicants respectfully remind the Examiner that section 103 requires consideration of the claimed invention "as a whole." This "as a whole" requirement prevents evaluation of the invention part by part, in hindsight. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698 (Fed. Cir. 1983). Without this requirement, an obviousness assessment could break an invention into its component parts (e.g., inhibiting *E. canis* infection), then find a prior art reference containing the component parts (e.g., SEQ ID NO:46, even though this sequence is not disclosed in Ohashi A, Ohashi B, or sequences referred to therein), and on that basis alone declare the invention obvious. The courts have refused to act on this type of hindsight reasoning, which uses the invention as a roadmap to find its prior art components. This type of analysis discounts the value of novel selection inventions. Thus, the courts have required that an Examiner must show some suggestion or motivation, excluding the invention itself, to make the new combination. See *In re Rouffet*, 149 F.3d 1350, 1355-56 (Fed. Cir. 1998); *In re Lee* 277 F. 2d 1338, 61 USPQ 2d 1430 (Fed. Cir. 2002); and c.f. *Ruiz v. A.B. Chance Co.*, F.3d 1270 (Fed. Cir. 2004).

Applicants assert that the mere fact that techniques were available and a skilled artisan may have been inquisitive and may have been led to further investigate the antigens does not provide motivation to achieve Applicants' novel invention. At best, the Examiner is improperly issuing an "obvious to try" rejection. The "obvious to try" standard has been held to constitute an improper ground for a 35 U.S.C. § 103 rejection. *In re O'Farrell*, 858, F.2d 894, 903 (Fed. Cir. 1988). An "obvious-to-try" situation exists when a general disclosure may pique an inventor's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching to obtain the desired result or indicate that the claimed result would be obtained if certain directions were pursued. *In re Eli Lilly & Co.*, 902 F.2d 943 (Fed. Cir. 1990).

Therefore, Applicants respectfully request withdrawal of the rejection.

III. Conclusion

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Applicants believe no fee is due with this response other than the fee for the Supplemental Information Disclosure Statement. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. AH-CLFR:181USD5 from which the undersigned is authorized to draw.

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Respectfully submitted,

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